NOAH Compendium

Norbrook Laboratories Ltd

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Betamox 150 mg/ml Suspension for Injection

Species: Cats, Cattle, Dogs, Pigs, Sheep

Therapeutic indication:Pharmaceuticals: Antimicrobials: Injections

Active ingredient: Amoxicillin

Product: Betamox 150 mg/ml Suspension for Injection

Product index: Betamox Injection

Cattle - milk:24 hours

Cattle - meat:18 days

Sheep - meat:10 days

Pig - meat:16 days

Withdrawal notes: Not for use in sheep producing milk for human consumption

Incorporating:

Qualitative and quantitative composition

Each ml contains

Active Substance:

Amoxicillin

(as Amoxicillin Trihydrate)

Excipients:

Butylated Hydroxyanisole

Butylated Hydroxytoluene	0.08

For a full list of excipients, see section "*Pharmaceutical Particulars"*

Pharmaceutical form

Suspension for injection.

An off-white oily suspension.

Clinical particulars

Target species

Cattle , Sheep, Pigs, Dogs, Cats

Indications for use, specifying the target species

For the treatment of infections caused by a wide range of Gram-positive and Gram-negative pathogenic bacteria including:

•*Actinobacillus equuli*

•*Actinomyces bovis*

•*Actinobacillus lignieresi*

•*Bacillus anthracis*

•*Erysipelothrix rhusiopathiae*

•*Bordetella bronchiseptica*

•*Escherichia coli*

•*Clostridium* species

•*Haemophilus* species

•*Corynebacterium* species

•*Pasteurella* species

•*Fusiformis* species

•*Proteus mirabilis*

•*Moraxella* species

•*Salmonella* species

•*Staphylococci*

•*Streptococci*

Not effective against beta-lactamase producing organisms.

Contraindications

Intravenous or intrathecal use.

Use in rabbits, hamsters, gerbils and guinea pigs.

Use in known cases of hypersensitivity to amoxycillin.

Special Warnings for each target species

None

Special precautions for use

Special precautions for use in animals

None

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately. Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations

Handle this product with great care to avoid exposure taking all recommended precautions.

If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

Adverse reactions (frequency and seriousness)

Occasional local tissue reactions may result from use of this product.

Penicillins and cephalosporins may cause hypersensitivity (allergy, allergic skin reactions) after use. Allergic reactions may occasionally be serious (anaphylaxis).

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Use during pregnancy, lactation or lay

Betamox Injection can be safely administered during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction

None known.

Amounts to be administered and administration route

•Cattle, sheep and pigs : By intramuscular injection only.

•Dogs and cats : By subcutaneous or intramuscular injection.

The recommended dosage rate is 7 mg/kg bodyweight once a day for up to five days. Massage the injection site.

A separate injection site should be used for each administration.

Animal	**Weight (kg)**	**Dose volume (ml)**
Cattle	450	20.0
Sheep	65	3.0
Pigs	150	7.0
Dogs	20	1.0
Cats	5	0.25

(Guide-dose volume is equivalent to about 0.25 ml per 5 kg daily).

Normal aseptic precautions should be observed. Shake vial before use. This product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry, sterile needle and syringe.

If dose volume exceeds 20 ml in cattle or 10 ml in pigs, it should be divided and injected into two sites.

Overdose (symptoms, emergency procedures, antidotes), if necessary

Penicillin’s have a wide safety margin

Withdrawal period

Milk for human consumption must not be taken from a cow during treatment. Milk for human consumption may only be taken after 24 hours from the last treatment.

Not for use in sheep producing milk for human consumption.

Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 18 days from the last treatment.

Sheep may be slaughtered for human consumption only after 10 days from the last treatment.

Pigs may be slaughtered for human consumption only after 16 days from the last treatment.

Pharmacological particulars

Pharmacotherapeutic group: Antibiotic

ATC Vet Code: QJ 01 CA 04

Pharmacodynamic properties

Amoxycillin predominately inhibits cell wall synthesis in susceptible bacteria. Amoxycillin has a unique mode of action which directly and irreversibly disrupts existing cell wall peptidoglycan rather than newly forming peptidoglycan of the divisory septal wall as with other members of the penicillin family.

Pharmaceutical particulars

List of excipients

•Butylated Hydroxyanisole

•Butylated Hydroxytoluene

•Aluminium Stearate

•Propylene Glycol Dicaprylocaprate

Incompatibilities

None known.

Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months

Shelf life after first opening the immediate packaging: 28 days

Special precautions for storage

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Do not store above 25°C.

Nature and composition of immediate packaging

Betamox Injection is supplied in 50 ml and 100 ml clear, colourless Type III or Type II glass vials, closed with nitrile rubber bungs and aluminium overseals, and 50 ml and 100 ml clear plastic vials closed with nitrile rubber bungs and aluminium overseals.

Not all pack sizes may be marketed.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

Marketing Authorisation Holder (if different from distributor)

Norbrook Laboratories Limited, Station Works, Camlough Road, Newry, Co. Down, BT35 6JP Northern Ireland

Marketing Authorisation Number

Vm 02000/4071

Significant changes

Date of the first authorisation or date of renewal

30 June 1986

Date of revision of the text

July 2025

Any other information

Nil.

Legal category

Legal category:POM-V

GTIN

GTIN description: Betamox 100ml

GTIN:5023534000433